

wherein said therapeutically effective amount causes a clinically significant improvement in a standard marker of renal function in said mammal.

2. (Amended) A method of treatment to delay the need for, or reduce the frequency of, chronic dialysis treatments comprising

administering to a mammal a therapeutically effective amount of an OP/BMP renal therapeutic agent,

wherein said OP/BMP renal therapeutic agent comprises a dimeric protein having an amino acid sequence having at least 70% amino acid sequence homology with the C-terminal seven-cysteine skeleton of human OP-1, amino acids 330-431 of SEQ ID NO:1;

wherein said renal therapeutic agent induces chondrogenesis in an *in vivo* ectopic bone assay; and

wherein said therapeutically effective amount causes a clinically significant improvement in a standard marker of renal function in said mammal.

3. (Amended) A method as in claim 1 wherein said renal therapeutic agent comprises a polypeptide [consisting of] comprising at least a C-terminal cysteine domain of a protein selected from the group consisting of a pro form, a mature form, and a soluble form of a polypeptide selected from the group consisting of OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6, and BMP9.

6. (Amended) A method as in claim [5] 1 wherein said [polypeptide] protein has at least 75% homology with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.

7. (Amended) A method as in claim [5] 1 wherein said [polypeptide] protein has at least 80% homology with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.
8. (Amended) A method as in claim [5] 1 wherein said [polypeptide] protein has at least 60% identity with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.
9. (Amended) A method as in claim [5] 1 wherein said [polypeptide] protein has at least 65% identity with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.
10. (Amended) A method as in claim [5] 1 wherein said [polypeptide] protein has at least 70% identity with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.
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*B4 cont*

## RESPONSE

Claims 1-17, 24, 28, and 32 were pending in the Application. Claim 5 is canceled, and claims 1-3 and 6-10 are amended by the present Amendment.

### Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-17, 24, 28 and 32 were rejected under 35 U.S.C. §112, first paragraph, for failing to enable "the claimed methods without regard to the structural and functional characteristics of the renal therapeutic agent." The Office Action noted, however, that the Specification is enabling for methods "comprising administering a dimeric protein wherein the subunits of said dimer comprise an amino acid having at least 70% amino acid sequence homology with the C-terminal seven cysteine domain of human OP-1, residues 330-431 of SEQ ID NO: 2 of U.S. Patent No. 5,266,683, and wherein said dimeric protein induces chondrogenesis in the Reddi-Sampath ectopic bone assay."